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AUG 20 2010

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: BRUCE SUNSTEIN
SUNSTEIN KANN MURPHY & TIMBERS LLP
125 SUMMER STREET
BOSTON, MA 02110

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 19 AUG 2010
Applicant's or agent's file reference 2960/A06WO	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2010/039587	International filing date *(day/month/year)* 23 June 2010
Applicant BOJARSKI, RAYMOND	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

   For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300
Facsimile No. 571-273-3201	Telephone No. PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 2960/A06WO	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2010/039587	International filing date *(day/month/year)* 23 June 2010	(Earliest) Priority Date *(day/month/year)* 24 June 2009
Applicant BOJARSKI, RAYMOND		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

   b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

   c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   ☒ the text is approved as submitted by the applicant.

   ☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No. 10A

   ☒ as suggested by the applicant.

   ☐ as selected by this Authority, because the applicant failed to suggest a figure.

   ☐ as selected by this Authority, because this figure better characterizes the invention.

   b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/039587

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/38 (2010.01)
USPC - 623/20.15
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61F 2/38 (2010.01)
USPC - 606/88; 623/20.14, 20.15, 20.31, 20.32

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/0058945 A1 (HAJAJ et al) 06 March 2008 (06.03.2008) entire document	16-31, 93-94
Y		1-15, 32-92
Y	US 7,105,026 B2 (JOHNSON et al) 12 September 2006 (12.09.2006) entire document	1-15, 54-86
Y	US 2007/0198022 A1 (LANG et al) 23 August 2007 (23.08.2007) entire document	32-92
Y	US 2008/0119940 A1 (OTTO et al) 22 May 2008 (22.05.2008) entire document	44, 46-48

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 August 2010	19 AUG 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

SUNSTEIN KANN MURPHY & TIMBERS LLP
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From the
INTERNATIONAL SEARCHING AUTHORITY

To: BRUCE SUNSTEIN
SUNSTEIN KANN MURPHY & TIMBERS LLP
125 SUMMER STREET
BOSTON, MA 02110

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	19 AUG 2010
Applicant's or agent's file reference 2960/A06WO	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2010/039587	23 June 2010	24 June 2009

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/38 (2010.01)
USPC - 623/20.15

Applicant BOJARSKI, RAYMOND

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	10 August 2010	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/039587

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/039587

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-15, 17-24, 28-92	YES
	Claims	16, 25-27, 93-94	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-94	NO
Industrial applicability (IA)	Claims	1-94	YES
	Claims	None	NO

2. Citations and explanations:

Claims 16, 25-27 and 93-94 lack novelty under PCT Article 33(2) as being anticipated by Hajaj et al. (henceforth Hajaj).

Regarding Claim 16, Hajaj discloses a tibial implant for knee arthroplasty (Fig. 5a), the tibial implant comprising: a) a medial tibial insert (modular tibial baseplate 11a and a modular tibial insert 11b to form the independent, stand-alone medial tibial component 11, Para. [0052]) comprising i) a substantially planar inner surface for engaging a medial tibial tray face (the interface between 11a and 11b is a flat surface as evident in Fig. 5a) and ii) an articular surface (upper surface of 11b) comprising an articular surface plateau (Figs. 3b&5a) and disposed therein a curved portion for opposing an articular surface of a medial femoral condyle (the concavely curved upper surface of a first tibial insert 11, which mates with the convexly curved surface of a femoral insert is best evident in Figs. 3a and 3c); and b) a lateral tibial insert (component 13 may be a lateral tibial component, including a baseplate 13a and an insert 13b, Fig. 5a and Para. [0057]) comprising i) a substantially planar inner surface for engaging a lateral tibial tray face (the interface between 13a and 13b is a flat surface as evident in Fig. 5a) and ii) an articular surface (upper surface of 13b) comprising an articular surface plateau (Figs. 3b&5a) and disposed therein a curved portion for opposing an articular surface of a lateral femoral condyle (the concavely curved upper surface a second tibial insert 13, which mates with the convexly curved surface of a femoral insert, is best evident in Figs. 3a and 3c); wherein the distance from the inner surface to the articular surface of the medial tibial insert is different from the distance from the inner surface to the articular surface of the lateral tibial insert (vary tibial insert thickness to thereby adjust a height of the insert, and to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]).

Regarding Claim 25, Hajaj discloses the tibial implant of Claim 16, and further teaches of a tibial implant wherein a first tibial tray (modular tibial baseplate 11a) comprises the medial tibial tray face (as evident in Fig. 5a) and a second tibial tray (modular tibial baseplate 13a) comprises the lateral tibial tray face (as evident in Fig. 5a).

Regarding Claim 26, Hajaj discloses the tibial implant of Claim 16, and further teaches of a tibial implant wherein medial and lateral tibial inserts have different curvatures in the respective curved portions (ability to vary curvature between components: the coronal curvature is substantially conforming to the curvature of the femur, while the sagittal curvature is less conforming to enable additional medial-lateral stability of the joint and correct for deficient collateral ligaments, Para. [0079]; also Para. [0082]).

Regarding Claim 27, Hajaj discloses the tibial implant of Claim 16, and further teaches of a tibial implant medial and lateral tibial inserts have different articular surface plateau slopes (vary curvature between components Para. [0079], and the location of the lowpoints may be changed by changing a slope of the tibial component, Para. [0081]).

Regarding Claim 93, Hajaj discloses a kit for implanting a tibial implant in a patient in need of knee replacement (Para. [0082]), the kit comprising: a) a tibial tray (tibial baseplate 13a, Fig. 5a and Para. [0052]) comprising a first surface for affixing the tray to the patient's tibia (bottom surface of 13a, Fig. 5a) and an opposing second surface for engaging a medial tibial insert (upper surface of 13a engages tibial insert 13b, Fig. 5a and Para. [0052]); and b) two or more medial tibial inserts having different thicknesses (different insert heights, Para. [0082]) from which to select one medial tibial insert (selection of segmented components for a surgeon to choose from in reestablishing the natural geometry and kinematics of a knee joint, Paragraphs [0070]-[0071]) for engaging with the tibial tray (as evident in Fig. 5a).

Regarding Claim 94, Hajaj discloses a kit for implanting a tibial implant in a patient in need of knee replacement (Para. [0082]), the kit comprising: a) a tibial tray (tibial baseplate 13a, Fig. 5a and Para. [0052]) comprising a first surface for affixing the tray to the patient's tibia (bottom surface of 13a, Fig. 5a) and an opposing second surface for engaging a lateral tibial insert (upper surface of 13a engages tibial insert 13b, Fig. 5a and Para. [0052]); and b) two or more lateral tibial inserts having different thicknesses (different insert heights, Para. [0082]) from which to select one lateral tibial insert (selection of segmented components for a surgeon to choose from in reestablishing the natural geometry and kinematics of a knee joint, Paragraphs [0070]-[0071]) for engaging with the tibial tray (as evident in Fig. 5a).

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Claims 17-24 and 28-31 lack an inventive step under PCT Article 33(3) as being obvious over Hajaj et al. (henceforth Hajaj).

Regarding Claim 17, Hajaj discloses the tibial implant of Claim 16, and further teaches of a tibial implant wherein the distance from the inner surface to the articular surface of the medial tibial insert is different from the distance from the inner surface to the articular surface of the lateral tibial insert (vary tibial insert thickness to thereby adjust a height of the insert, and to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]); but fails to explicitly teach wherein the distance is a minimum distance. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow a measurement for comparing medial and lateral tibial inserts to be based on a minimum distance, to provide optimal balancing and alignment of a reconstructed knee joint, since discovering the optimum value of a result effective variable involves only routine skill in the art.

Regarding Claim 18, Hajaj discloses the tibial implant of Claim 16, and further teaches of a tibial implant wherein the distance from the inner surface to the articular surface of the medial tibial insert is different from the distance from the inner surface to the articular surface of the lateral tibial insert (vary tibial insert thickness to thereby adjust a height of the insert, and to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]); but fails to explicitly teach wherein the distance is a maximum distance. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow a measurement for comparing medial and lateral tibial inserts to be based on a maximum distance, to provide optimal balancing and alignment of a reconstructed knee joint, since discovering the optimum value of a result effective variable involves only routine skill in the art.

Regarding Claim 19, Hajaj discloses the tibial implant of Claim 16, and further teaches of a tibial implant wherein the distance from the inner surface to the articular surface of the medial tibial insert, is different from the distance from the inner surface to the articular surface of the lateral tibial insert (vary tibial insert thickness to thereby adjust a height of the insert, and to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]); but fails to explicitly teach wherein the distance is a average distance. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow a measurement for comparing medial and lateral tibial inserts to be based on an average distance, to provide optimal balancing and alignment of a reconstructed knee joint, since discovering the optimum value of a result effective variable involves only routine skill in the art.

Regarding Claim 20, Hajaj discloses the tibial implant of Claim 16, but fails to explicitly teach of a tibial implant wherein the distance from the inner surface to the articular surface of the medial tibial insert is substantially different from the distance from the inner surface to the articular surface of the lateral tibial insert. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the distance from the inner surface to the articular surface of ta medial tibial insert, i.e., the medial insert thickness, to be substantially different from the distance from the inner surface to the articular surface of a lateral tibial insert, i.e., the lateral insert thickness, to provide optimal balancing and alignment of a reconstructed knee joint, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding Claim 21, Hajaj discloses the tibial implant of Claim 16, but fails to explicitly teach of a tibial implant wherein the distance from the inner surface to the articular surface of the medial tibial insert is significantly different from the distance from the inner surface to the articular surface of the lateral tibial insert. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the distance from the inner surface to the articular surface of a medial tibial insert, i.e., the medial insert thickness, to be significantly different from the distance from the inner surface to the articular surface of a lateral tibial insert, i.e., the lateral insert thickness, to provide optimal balancing and alignment of a reconstructed knee joint, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding Claim 22, Hajaj discloses the tibial implant of Claim 16, and further teaches of a tibial implant wherein the distance from the inner surface to a point of the articular surface of the medial tibial insert is different from the distance from the inner surface to a point of the articular surface of the lateral tibial insert (vary tibial insert thickness to thereby adjust a height of the insert, and to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]); but fails to explicitly teach wherein the point is a central point. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow a measurement for comparing medial and lateral tibial inserts to be based on a central point as a reference point, to aid in balancing and alignment a knee joint reconstruction, since defining a reference point from which to make a measurement is well known in the art.

Regarding Claim 23, Hajaj discloses the tibial implant of Claim 16, and further teaches of a tibial implant wherein the distance from the inner surface to a point of a contact area of the articular surface of the medial tibial insert is different from the distance from the inner surface to a point of a contact area of the articular surface of the lateral tibial insert (vary tibial insert thickness to thereby adjust a height of the insert, and to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]); but fails to explicitly teach wherein the point is a central point. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow a measurement for comparing medial and lateral tibial inserts to be based on a central point as a reference point, to aid in balancing and alignment a knee joint reconstruction, since defining a reference point from which to make a measurement is well known in the art.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Regarding Claim 24, Hajaj discloses the tibial implant of Claim 16, and further teaches of a tibial implant the distance from the inner surface to a point of the articular surface of the medial tibial insert is different from the distance from the inner surface to a point of the articular surface of the lateral tibial insert (vary tibial insert thickness to thereby adjust a height of the insert, and to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]); but fails to explicitly teach wherein the point is an edge. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow measurements of the thickness to be from the inner surface to an edge of the articular surface as a reference point, to aid in balancing and alignment a knee joint reconstruction, since defining a reference point from which to make a measurement is well known in the art.

Regarding Claim 28, Hajaj discloses the tibial implant of Claim 16, and further teaches of a tibial implant wherein the medial tibial insert is patient-matched (a prosthetic device having a precise fit for each patient, Para. [0070]; the surgeon can alter the geometry, conformity, and/or configuration of the prosthetic device to meet the customized needs of the patient in each region of the joint, Para. [0071]); but fails to explicitly teach wherein the slope for the articular surface plateau of the medial tibial insert is patient-matched to the patient's medial tibial plateau slope. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the geometry of a patient's natural tibial plateau slope to be exactly represented in a medial tibial insert, to provide optimal balancing and alignment of a reconstructed knee joint, since the custom design of part or all of an implant is well known in the art.

Regarding Claim 29, Hajaj discloses the tibial implant of Claim 16, and further teaches of a tibial implant wherein the medial tibial insert is patient-matched (a prosthetic device having a precise fit for each patient, Para. [0070]; the surgeon can alter the geometry, conformity, and/or configuration of the prosthetic device to meet the customized needs of the patient in each region of the joint, Para. [0071]); but fails to explicitly teach wherein the slope for the articular surface plateau of the medial tibial insert is patient-matched to the patient's lateral tibial plateau slope. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the geometry of a patient's natural lateral tibial plateau slope to be exactly represented in a medial tibial insert, to provide optimal balancing and alignment of a reconstructed knee joint, since the custom design of part or all of an implant is well known in the art.

Regarding Claim 30, Hajaj discloses the tibial implant of Claim 16, and further teaches of a tibial implant wherein the medial tibial insert is patient-matched (a prosthetic device having a precise fit for each patient , Para. [0070]; the surgeon can alter the geometry, conformity, and/or configuration of the prosthetic device to meet the customized needs of the patient in each region of the joint, Para. [0071]); but fails to explicitly teach wherein the slope for the articular surface plateau of the lateral tibial insert is patient-matched to the patient's lateral tibial plateau slope. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the geometry of a patient's natural lateral tibial plateau slope to be exactly represented in a lateral tibial insert, to provide optimal balancing and alignment of a reconstructed knee joint, since the custom design of part or all of an implant is well known in the art.

Regarding Claim 31, Hajaj discloses the tibial implant of Claim 16, and further teaches of a tibial implant wherein the medial tibial insert is patient-matched (a prosthetic device having a precise fit for each patient , Para. [0070]; the surgeon can alter the geometry, conformity, and/or configuration of the prosthetic device to meet the customized needs of the patient in each region of the joint, Para. [0071]); but fails to explicitly teach wherein the slope for the articular surface plateau of the lateral tibial insert is patient-matched to the patient's medial tibial plateau slope. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the geometric feature of a patient's natural medial tibial plateau slope to be exactly represented in a lateral tibial insert, to provide optimal balancing and alignment of a reconstructed knee joint, since the custom design of part or all of an implant is well known in the art.

Claims 1-15 lack an inventive step under PCT Article 33(3) as being obvious over Johnson et al. (henceforth Johnson) modified by Hajaj et al. (henceforth Hajaj).

Regarding Claim 1, Johnson discloses a tibial implant (404/420/422, Fig. 20B) for knee arthroplasty (prosthetic knee system, Abstract), the tibial implant comprising: a) a tibial tray (422) sized and shaped generally for placement on a proximal surface of a tibia of a patient (fastening baseplate 422 to the tibial bone, Col. 11, Lns. 7-10) and having at least one insert locking mechanism (shoulder 441, Col. 11, Lns. 40-45); b) a first insert (lateral component 450 of tibial insert 420, Figs. 20A/20C) comprising a first reciprocal locking mechanism (A ledge 468 extends around the outer perimeter and is adapted to engage shoulder 441 when tibial insert 420 and tibial baseplate 422 are connected together, Fig. 20B Col. 11, Lns. 40-45), a first bottom surface (bottom of 450) for engaging a surface of the tibial tray (A generally planar surface 464 is oppositely disposed from the condylar surface and is adapted to engage and connect to surface 440 of the tibial baseplate, Col. 11, Lns. 36-39), a first articular surface portion (460A) generally opposite the first base surface (as evident in Fig. 20C), and a first thickness extending in a generally perpendicular direction between the first bottom surface and the first articular surface (thickness of 450 in Fig. 20C); and c) a second insert (medial component 452 of tibial insert 420, Figs. 20A/20C) comprising a second reciprocal locking mechanism (shoulder 441, Col. 11, Lns. 40-45), a second bottom surface (bottom of 452) for engaging a surface of the tibial tray (Col. 11, Lns. 36-39), a second articular surface portion (460B) generally opposite the second base surface (as evident in Fig. 20C), and a second thickness extending in a generally perpendicular direction between the second bottom surface and the second articular surface (thickness of 452 in Fig. 20C); but fails to explicitly teach of a tibial implant wherein the first thickness is greater than the second thickness. Hajaj, however, teaches of a tibial implant wherein a first thickness is greater than a second thickness (vary tibial insert thickness to thereby adjust a height of the insert, and to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the different tibial insert thicknesses of Hajaj with the disclosure of Johnson to aid in creating a knee prosthesis capable of providing improved medial-lateral joint stability.

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:

Regarding Claim 2, Johnson modified by Hajaj discloses the tibial tray of Claim 1, but fails to explicitly teach of a tibial implant wherein the first and second thicknesses are measured from geographic centers of the first and second contact areas of the first and second articular surfaces, respectively. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow measurements of the thicknesses of first and second tibial inserts, for comparison purposes, to be with respect to a reference point such as the geographic centers of the first and second contact areas of the first and second articular surfaces, respectively, to aid in providing a patient specific tibial insert for optimal balancing and alignment of reconstructed knee joint, since defining a reference point from which to make a measurement is well known in the art.

Regarding Claim 3, Johnson modified by Hajaj discloses the tibial tray of Claim 1, but fails to explicitly teach of a tibial implant wherein the first and second thicknesses are measured from corresponding edges of first and second contact areas of the first and second articular surfaces, respectively. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow measurements of the thicknesses of first and second tibial inserts, for comparison purposes, to be with respect to a reference point such as the edges of the first and second contact areas of the first and second articular surfaces, respectively, to aid in providing a patient specific tibial insert for optimal balancing and alignment of reconstructed knee joint, since defining a reference point from which to make a measurement is well known in the art.

Regarding Claim 4, Johnson modified by Hajaj discloses the tibial tray of Claim 1, but fails to explicitly teach of a tibial implant wherein the first and second thicknesses are measured from central points of the first and second articular surfaces, respectively. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow measurements of the thicknesses of first and second tibial inserts, for comparison purposes, to be with respect to a reference point such as the central points of the first and second contact areas of the first and second articular surfaces, respectively, to aid in providing a patient specific tibial insert for optimal balancing and alignment of reconstructed knee joint, since defining a reference point from which to make a measurement is well known in the art.

Regarding Claim 5, Johnson modified by Hajaj discloses the tibial tray of Claim 1, but fails to explicitly teach of a tibial implant wherein the first and second thicknesses are measured from the point of the first and second articular surfaces that are closest to the first and second bottom surfaces, respectively. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow measurements of the thicknesses of first and second tibial inserts, for comparison purposes, to be with respect toa reference piont, such as from the point of the first and second articular surfaces that are closest to the first and second bottom surfaces, to aid in providing a patient specific tibial insert for optimal balancing and alignment of reconstructed knee joint, since defining a reference point from which to make a measurement is well known in the art.

Regarding Claim 6, Johnson modified by Hajaj discloses the tibial tray of Claim 1, but fails to explicitly teach of a tibial implant wherein the first and second thicknesses are measured from the point of the first and second articular surfaces that are furthest from the first and second bottom surfaces, respectively. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow measurements of the thicknesses of first and second tibial inserts, for comparison purposes, to be with respect to a reference point, such as the point of the first and second articular surfaces that are furthest from the first and second bottom surfaces, respectively, to aid in providing a patient specific tibial insert for optimal balancing and alignment of reconstructed knee joint, since defining a reference point from which to make a measurement is well known in the art.

Regarding Claim 7, Johnson modified by Hajaj discloses the tibial tray of Claim 1, but fails to explicitly teach of a tibial implant wherein the first and second thicknesses are average thicknesses of the first and second inserts, respectively. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow first and second thicknesses to be average thicknesses of the first and second inserts, respectively, to aid in optimally balancing and aligning a reconstructed knee joint, since the use of average thicknesses is well known in the art.

Regarding Claim 8, Johnson modified by Hajaj discloses the tibial tray of Claim 1, but fails to explicitly teach of a tibial implant wherein the first thickness is substantially greater than the second thickness. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the thicknesses of a first tibial insert to be substantially greater than a second tibial insert, to provide optimal balancing and alignment of a reconstructed knee joint, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding Claim 9, Johnson modified by Hajaj discloses the tibial tray of Claim 1, but fails to explicitly teach of a tibial implant wherein a difference in the thickness of the first and second thicknesses is a statistically significant difference. It would have been obvious to one of ordinary skill in the art at the time the invention was made to allow the difference in thicknesses of first and second tibial inserts to be a statistically significant difference, to provide optimal balancing and alignment of a reconstructed knee joint, since where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Regarding Claim 10, Johnson modified by Hajaj discloses the tibial tray of Claim 1. Johnson fails to explicitly teach of a tibial implant wherein a difference in the thickness of the first and second thicknesses is a clinically significant difference. Hajaj, however, teaches of a tibial implant wherein the difference in thickness of first and second insert thicknesses is a clinically significant difference (to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the different tibial insert thicknesses of Hajaj with the disclosure of Johnson to aid in creating a knee prosthesis capable of providing improved medial-lateral joint stability.

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Regarding Claim 11, Johnson modified by Hajaj discloses the tibial tray of Claim 1. Johnson fails to explicitly teach of a tibial implant wherein a difference in the thickness of the first and second thicknesses is sufficient to induce a clinical effect. Hajaj, however, teaches of a tibial implant wherein a difference in thickness of first and second insert thicknesses is sufficient to induce a clinical effect (to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the different tibial insert thicknesses of Hajaj with the disclosure of Johnson to provide additional medial-lateral joint stability.

Regarding Claim 12, Johnson modified by Hajaj discloses the tibial tray of Claim 11. Johnson fails to explicitly teach of a tibial implant wherein the clinical effect is an alignment of at least a portion of the knee. Hajaj, however, teaches of a tibial implant wherein the clinical effect is an alignment of at least a portion of the knee (to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the knee joint alignment approach of Hajaj with the disclosure of Johnson to provide additional medial-lateral joint stability.

Regarding Claim 13, Johnson modified by Hajaj discloses the tibial tray of Claim 11. Johnson fails to explicitly teach of a tibial implant wherein the clinical effect is a balancing of at least a portion of the knee. Hajaj, however, teaches of a tibial implant wherein the clinical effect is a balancing of at least a portion of the knee (to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments to correct for deformaties such as vargus and valgus, Para. [0082]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the knee joint balancing approach of Hajaj with the disclosure of Johnson to provide additional medial-lateral joint stability.

Regarding Claim 14, Johnson modified by Hajaj discloses the tibial tray of Claim 1. Johnson fails to explicitly teach of a tibial implant wherein the first and second inserts have different curvatures on respective articular surface portions. Hajaj, however, teaches of a tibial implant wherein first and second inserts have different curvatures on respective articular surface portions (ability to vary curvature between components: the coronal curvature is substantially conforming to the curvature of the femur, while the sagittal curvature is less conforming to enable additional medial-lateral stability of the joint and correct for deficient collateral ligaments, Para. [0079]; also Para. [0090]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the different articular surface curvatures of Hajaj with the disclosure of Johnson to provide additional medial-lateral joint stability.

Regarding Claim 15, Johnson modified by Hajaj discloses the tibial tray of Claim 1. Johnson fails to explicitly teach of a tibial implant wherein the first and second inserts have different slopes on respective articular surface portions. Hajaj, however, teaches of a tibial implant wherein first and second inserts have different slopes on respective articular surface portions (vary curvature between components Para. [0079], and the location of the lowpoints may be changed by changing a slope of the tibial component, Para. [0081]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the knee joint alignment approach of Hajaj with the disclosure of Johnson to provide additional medial-lateral joint stability.

Claims 32-43, 45, 49-53 and 87-92 lack an inventive step under PCT Article 33(3) as being obvious over Lang et al. (henceforth Lang) modified by Hajaj et al. (henceforth Hajaj).

Regarding Claim 32, Lang discloses a method for making a tibial implant (tibial implant 2415, Para. [0154]) for use in repairing or replacing a knee of a patient (joint arthroplasty, Cl. 61), comprising: a) electronically evaluating at least a portion of the knee based on image data of the knee (imaging and analysis to determine the dimensions and shape of a joint, Paragraphs [0190]-[0191]); and b) specifying one or more parameters of the tibial implant based at least in part on the evaluation (The dimensions, overall size and shape of an implant may be optimized with regard to cortical bone shape and dimensions, cortical bone thickness, endosteal bone shape, size of marrow cavity, articular surface shape and dimensions, subchondral bone shape and dimensions, or subchondral bone thickness. Thus, for example, an implant may be custom made, Para. [0191]); wherein the specified parameters define at least in part a tibial implant (tibial implant 2415, Para. [0154]); but fails to explicitly teach of a tibial implant having a first articular surface higher than a second articular surface relative to a proximal end of a tibia of the knee when the tibial implant is implanted on the proximal end of the tibia. Hajaj, however, teaches of a tibial implant having a first articular surface higher than a second articular surface relative to a proximal end of a tibia of the knee when the tibial implant is implanted on the proximal end of the tibia (to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the different tibial insert thicknesses of Hajaj with the disclosure of Lang to provide additional medial-lateral joint stability.

Regarding Claim 33, Lang modified by Hajaj discloses the method of Claim 32. Lang further teaches wherein a method further comprises planning a surgical result (surgical planning, Para. [0068]) based on the electronic image data of a patient's knee (imaging of knee joint, Paragraphs [0063] and [0198]).

Regarding Claim 34, Lang modified by Hajaj discloses the method of Claim 32. Lang further teaches of a method wherein the specified parameters (Para. [0191]) define at least in part a configuration of a tibial implant to substantially achieve a planned surgical result (These parameters may also be optimized for implant function, e.g., for different degrees of joint flexion or extension, Para. [0191]).

Regarding Claim 35, Lang modified by Hajaj discloses the method of Claim 34. Lang further teaches of a method wherein the surgical result is knee balancing during a surgical procedure (ligament balancing, Para. [0423]).

Regarding Claim 36, Lang modified by Hajaj discloses the method of Claim 35. Lang further teaches of a method wherein the knee balancing comprises knee balancing during extension (ligament balancing, Para. [0423]).

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Regarding Claim 37, Lang modified by Hajaj discloses the method of Claim 35. Lang further teaches of a method wherein the knee balancing comprises knee balancing during flexion (ligament balancing, Para. [0423]).

Regarding Claim 38, Lang modified by Hajaj discloses the method of Claim 34. Lang further teaches of a method wherein the surgical result is knee alignment (joint alignment, Para. [0423]).

Regarding Claim 39, Lang modified by Hajaj discloses the method of Claim 38. Lang further teaches of a method wherein the knee alignment comprises knee alignment of anatomical axes (Paragraphs [0435], [0438] and [0439]).

Regarding Claim 40, Lang modified by Hajaj discloses the method of Claim 38. Lang further teaches of a method wherein the knee alignment comprises knee alignment of biomechanical axes (Paragraphs [0435], [0438] and [0439]).

Regarding Claim 41, Lang modified by Hajaj discloses the method of Claim 38. Lang further teaches of a method wherein the knee alignment comprises knee alignment of femur and tibia (total knee replacement involving femoral and tibial component rotation, Claims 97-98 and 101-103).

Regarding Claim 42, Lang modified by Hajaj discloses the method of Claim 41. Lang further teaches of a method wherein the alignment of femur and tibia comprises linear alignment of femur and tibia (correcting axis of alignment during joint arthroplasty, Cl. 47, and correction may, for example, be designed to achieve a result wherein the femoral 3801 and tibial 3803 axes will coincide with the biomechanical axis 3805, Para. [0495]).

Regarding Claim 43, Lang modified by Hajaj discloses the method of Claim 41. Lang further teaches of a method wherein the alignment of femur and tibia comprises rotational alignment of femur and tibia (total knee replacement involving femoral and tibial component rotation, Claims 97-98 and 101-103).

Regarding Claim 45, Lang modified by Hajaj discloses the method of Claim 32. Lang further teaches of a method wherein the electronically evaluating at least a portion of the knee comprises determining a difference in the relative position of at least a portion of first and second articular surfaces of the knee (imaging and analysis to determine the dimensions and shape of a joint, Paragraphs [0190]-[0191]).

Regarding Claim 49, Lang discloses a method for making a tibial implant (2415, Para. [0154]) that substantially matches a patient's biological feature in one or more measurements (Generate a custom, patient specific implant 34, Fig. 1), or as a predetermined percentage thereof, the method comprising: a) preoperatively identifying a feature measurement of the patient's joint (determining joint space width of a knee joint using imaging scans, the medial and lateral joint space width may be compared and differences in medial and lateral joint space width can be utilized to optimize the desired postoperative correction in anatomical or biomechanical axis alignment based on this information, Para. [0228]; also Para. [0191]); and b) designing an implant template to include substantially the same feature measurement or a predetermined percentage of the feature measurement identified in step a) (custom implant template made based on imaging data of patient bone geometry, including the mediolateral dimensions and shape, Para. [0191]); but fails to explicitly teach wherein the designing involves at least one of the medial tibial insert and the lateral tibial insert. Hajaj, however, teaches of designing at least one of a medial tibial insert and a lateral tibial insert (The medial tibial component 32 may be designed and manufactured with a variety of contours, Para. [0076]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the tibial insert designs of Hajaj with the disclosure of Lang to aid in creating a knee prosthesis capable of providing improved medial-lateral joint stability.

Regarding Claim 50, Lang modified by Hajaj discloses the method of Claim 49. Lang further teaches of a method wherein designing the at least one of the medial tibial insert and lateral tibial insert comprises computer-aided design/CAD and computer-aided manufacturing/CAM (the articular repair system is either selected - based on best fit- from a catalogue of existing, pre-made implants with a range of different sizes and curvatures or custom-designed using CAD/CAM technology. The library of existing shapes is typically on the order of about 30 sizes, Para. [0685]).

Regarding Claim 51, Lang modified by Hajaj discloses the method of Claim 49. Lang further teaches of a method wherein designing the at least one of the medial tibial insert and lateral tibial insert comprises cutting the feature measurement from a blank (the use of rapid prototyping, Para. [0051], and CAD/CAM technology, Para. [0685], allows customized trial tibial inserts to be produced).

Regarding Claim 52, Lang modified by Hajaj discloses the method of Claim 49. Lang further teaches of a method wherein the substantially matching feature measurement is selected from the group consisting of: an insert mediolateral dimension substantially matching a corresponding patient mediolateral dimension or a predetermined percentage thereof (Implant design based on imaging data of patient bone geometry, including the mediolateral dimensions and shape, Para. [0191]), an insert thickness substantially matching a corresponding thickness of resected patient tissue or a predetermined percentage thereof, an insert perimeter shape substantially matching a corresponding patient perimeter shape or a predetermined percentage thereof, an insert surface slope substantially matching a corresponding patient slope or a predetermined percentage thereof, and an insert surface curvature substantially matching a corresponding patient curvature or a predetermined percentage thereof.

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Regarding Claim 53, Lang modified by Hajaj discloses the method of Claim 49. Lang further teaches of a method wherein substantially matching includes optimizing smoothing a line or curve of the patient's biological feature (smoothing operation, Para. [0237]).

Regarding Claim 87, Lang discloses a method for balancing or optimizing ligament tension during implantation of a knee implant in a patient (ligament balancing, Cl. 87), the method comprising the steps of: a) assessing the patient's medial joint gap distance and tension (determining joint space width of a knee joint using imaging scans, the medial and lateral joint space width may be compared and differences in medial and lateral joint space width can be utilized to optimize the desired postoperative correction in anatomical or biomechanical axis alignment based on this information, Para. [0228] and also Para. [0191], and use of imaging data to aid in ligament balancing, Para. [0107]); b) assessing the patient's lateral joint gap distance and tension (Paragraphs [0107], [0191] and [0228]); but fails to explicitly teach of method with the step of c) selecting independent medial and lateral tibial inserts to provide proper gap distance and tension. Hajaj, however, teaches of selecting independent medial and lateral tibial inserts to provide proper gap distance and tension (vary tibial insert thickness to thereby adjust a height of the insert, and to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the tibial inserts with different insert thicknesses approach of Hajaj with the disclosure of Lang to aid in creating a knee prosthesis capable of providing improved medial-lateral joint stability.

Regarding Claim 88, Lang modified by Hajaj discloses the method of Claim 87. Lang fails to explicitly teach of a method wherein the selected medial and lateral tibial inserts have different thicknesses. Hajaj, however, teaches of a method wherein medial and lateral tibial inserts have different thicknesses (vary tibial insert thickness to thereby adjust a height of the insert, and to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the tibial inserts with different thicknesses approach of Hajaj with the disclosure of Lang to aid in creating a knee prosthesis capable of providing improved medial-lateral joint stability.

Regarding Claim 89, Lang modified by Hajaj discloses the method of Claim 87. Lang fails to explicitly teach of a method wherein in step c) the selected medial tibial insert is selected from among two or more medial tibial inserts having different thicknesses. Hajaj, however, teaches wherein the selected medial tibial insert is selected from among two or more medial tibial inserts having different thicknesses (vary tibial insert thickness to thereby adjust a height of the insert, and to achieve ligament balance, Para. [0082]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the tibial inserts with different thicknesses approach of Hajaj with the disclosure of Lang to aid in creating a knee prosthesis capable of providing improved medial-lateral joint stability.

Regarding Claim 90, Lang modified by Hajaj discloses the method of Claim 87. Lang fails to explicitly teach of a method wherein in step c) the selected lateral tibial insert is selected from among two or more lateral tibial insert having different thicknesses. Hajaj, however, teaches wherein the selected lateral tibial insert is selected from among two or more lateral tibial insert having different thicknesses (vary tibial insert thickness to thereby adjust a height of the insert, and to achieve ligament balance, Para. [0082]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the tibial inserts with different thicknesses approach of Hajaj with the disclosure of Lang to aid in creating a knee prosthesis capable of providing improved medial-lateral joint stability.

Regarding Claim 91, Lang modified by Hajaj discloses the method of Claim 87. Lang fails to explicitly teach of a method wherein the selection of one or both medial and lateral tibial inserts substantially restores the patient's natural medial and lateral joint gaps. Hajaj, however, teaches wherein the selection of one or both medial and lateral tibial inserts substantially restores the patient's natural medial and lateral joint gaps (the implanted components of the prosthetic device enable optimal restoration of joint kinematics based on patient anatomy and previous joint function, Para. [0072]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the tibial inserts with different thicknesses approach of Hajaj with the disclosure of Lang to aid in creating a knee prosthesis capable of providing improved medial-lateral joint stability.

Regarding Claim 92, Lang modified by Hajaj discloses the method of Claim 87. Lang fails to explicitly teach of a method wherein the selection of one or both medial and lateral tibial inserts substantially restores the patient's natural kinematics. Hajaj, however, teaches wherein the selection of one or both medial and lateral tibial inserts substantially restores the patient's natural kinematics (the implanted components of the prosthetic device enable optimal restoration of joint kinematics based on patient anatomy and previous joint function, Para. [0072]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the tibial inserts with different thicknesses approach of Hajaj with the disclosure of Lang to aid in creating a knee prosthesis capable of providing improved medial-lateral joint stability.

Claims 44 and 46-48 lack an inventive step under PCT Article 33(3) as being obvious over Lang et al. (henceforth Lang) modified by Hajaj et al. (henceforth Hajaj) and Otto et al. (henceforth Otto).

Regarding Claim 44, Lang modified by Hajaj discloses the method of Claim 34, but fails to explicitly teach of a method wherein the surgical result comprises establishment of a joint line of a medial compartment of the knee relative to a lateral compartment of the knee. Otto, however, teaches of a method wherein a surgical result comprises establishment of a joint line of a medial compartment of the knee relative to a lateral compartment of the knee (joint line established by prostheses according to certain embodiments and aspects of the invention preferably replicate this physiological joint line 227, Para. [0080]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the joint line establishment approach of Otto with the disclosure of Lang to aid in properly implanting a knee prosthesis capable of providing improved medial-lateral joint stability.

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Regarding Claim 46, Lang modified by Hajaj discloses the method of Claim 32. Lang further teaches of a method wherein the electronically evaluating at least a portion of the knee comprises determining a feature of the knee (obtaining image data of the knee, Para. [0093]); but fails to explicitly teach wherein the feature is the joint line. Otto, however, teaches of a method wherein a surgical result comprises establishment of a knee joint line (joint line established by prostheses according to certain embodiments and aspects of the invention preferably replicate this physiological joint line 227, Para. [0080]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the monitoring of the joint line approach of Otto with the disclosure of Lang to aid in properly implanting a knee prosthesis capable of providing improved medial-lateral joint stability.

Regarding Claim 47, Lang modified by Hajaj and Otto discloses the method of Claim 46, but fails to explicitly teach wherein determining a joint line of the knee comprises presurgically determining a joint line of the knee. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the imaging techniques of Lang in Claim 46 to determine the joint line of a knee, as per Otto in Claim 46, prior to surgery, to aid a surgeon in correctly placing an implant while minimizing tissue trauma, since using imaging techniques to determine joint features preoperatively is well known in the art.

Regarding Claim 48, Lang modified by Hajaj and Otto discloses the method of Claim 46, but fails to explicitly teach wherein determining a joint line of the knee comprises postsurgically determining a joint line of the knee. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the imaging techniques of Lang in Claim 46 to determine the joint line of the knee, as per Otto in Claim 46, following surgery, to evaluate the success of a surgical procedure, since using imaging techniques to determine joint features postoperatively is well known in the art.

Claims 54-86 lack an inventive step under PCT Article 33(3) as being obvious over Lang et al. (henceforth Lang) modified by Johnson et al. (henceforth Johnson) and Hajaj et al. (henceforth Hajaj).

Regarding Claim 54, Lang discloses a method for implanting a knee implant in a patient's knee (tibial implant 2415, Para. [0154]), the method comprising the steps of: a) preparing a proximal end of a tibia to receive an implant (use of templates and cutting guides for cutting the tibia and forming anchoring apertures, Paragraphs [0615]-[0616]; also 2140 in Fig. 23); and b) inserting at least one tibial implant onto the prepared proximal end of the tibia (tibial implant inserted with pegs pointing into drilled holes, Paragraphs [0690]-[0691]; also 2142 in Fig. 23); but fails to explicitly teach of insertion of at least one tibial implant such that a first articular surface of the at least one implant engages a first articular surface of a femur or femoral implant and a second articular surface of the at least one implant engages a second articular surface of the femur or femoral implant; and wherein the first articular surface is higher than the second articular surface relative to an anatomical axis of the tibia. Johnson, however, teaches of insertion of at least one tibial implant (prosthetic knee system implantable in a knee using minimally invasive surgery, Cl. 16 and Fig. 21A) such that a first articular surface of the at least one implant engages a first articular surface of a femur or femoral implant (left component of 504 engages 502, Fig. 21A and Col. 12, Lns. 5-11) and a second articular surface of the at least one implant engages a second articular surface of the femur or femoral implant (right component of 504 engages 502, Fig. 21A and Col. 12, Lns. 5-11). In addition, Hajaj teaches of a tibial implant wherein a first articular surface is higher than a second articular surface relative to an anatomical axis of the tibia (to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the modular knee implant of Johnson and the tibial insert thickness approach of Hajaj with the disclosure of Lang to provide additional medial-lateral joint stability.

Regarding Claim 55, Lang modified by Johnson and Hajaj discloses the method of Claim 54. Lang fails to explicitly teach of a method wherein the at least one tibial implant comprises a single tibial implant tray. Hajaj, however, teaches of a method wherein at least one tibial implant comprises a single tibial implant tray (502a, Fig. 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the single tibial tray approach of Hajaj with the disclosure of Lang to create a knee prosthesis capable of providing improved medial-lateral joint stability.

Regarding Claim 56, Lang modified by Johnson and Hajaj discloses the method of Claim 55. Lang fails to explicitly teach of a method further comprising a single tibial insert. Hajaj, however, teaches of a tibial implant further comprising a single tibial insert (502b, Fig. 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the single tibial insert approach of Hajaj with the disclosure of Lang to create a knee prosthesis capable of providing improved medial-lateral joint stability.

Regarding Claim 57, Lang modified by Johnson and Hajaj discloses the method of Claim 55. Lang fails to explicitly teach of a method further comprising dual tibial insert. Hajaj, however, teaches of a tibial implant further comprising dual tibial inserts (11b/13b, Fig. 5a). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the dual tibial insert approach of Hajaj with the disclosure of Lang to create a knee prosthesis capable of providing improved medial-lateral joint stability.

Regarding Claim 58, Lang modified by Johnson and Hajaj discloses the method of Claim 54. Lang fails to explicitly teach of a method wherein the at least one tibial implant comprises two tibial implant trays. Hajaj, however, teaches of a tibial implant further comprising two tibial implant trays (11a/13a, Fig. 5a). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the dual tibial tray approach of Hajaj with the disclosure of Lang to create a knee prosthesis capable of providing improved medial-lateral joint stability.

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Regarding Claim 59, Lang modified by Johnson and Hajaj discloses the method of Claim 58. Lang fails to explicitly teach of a method further comprising a single tibial insert for each of the two tibial implant trays. Hajaj, however, teaches of a tibial implant further comprising a single tibial insert for each of two tibial implant trays (11b/13b reside within 11a/13a, respectively, Fig. 5a). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the dual tibial insert and tray approach of Hajaj with the disclosure of Lang to create a knee prosthesis capable of providing improved medial-lateral joint stability.

Regarding Claim 60, Lang modified by Johnson and Hajaj discloses the method of Claim 54. Lang fails to explicitly teach of a method further comprising adjusting height of first articular surface relative to second articular surface. Hajaj, however, teaches of a further comprising adjusting the height of a first articular surface relative to a second articular surface (vary tibial insert thickness to thereby adjust a height of the insert, and to achieve ligament balance, different insert thicknesses can be used in each of the medial and lateral compartments, Para. [0082]). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the different insert thicknesses of Hajaj with the disclosure of Lang to aid in creating a knee prosthesis capable of providing improved medial-lateral joint stability.

Regarding Claim 61, Lang modified by Johnson and Hajaj discloses the method of Claim 54. Lang further teaches of a method further comprising aligning the patient's joint (joint alignment, Para. [0423]).

Regarding Claim 62, Lang modified by Johnson and Hajaj discloses the method of Claim 61. Lang further teaches of a method further comprising assessing the alignment of the patient's joint (determining joint space width of a knee joint using imaging scans, the medial and lateral joint space width may be compared and differences in medial and lateral joint space width can be utilized to optimize the desired postoperative correction in anatomical or biomechanical axis alignment based on this information, Para. [0228]).

Regarding Claim 63, Lang modified by Johnson and Hajaj discloses the method of Claim 61. Lang further teaches of a method further comprising adjusting alignment of the patient's joint (subsequent adjustments and fine-tuning of surgical intervention, Para. [0496]).

Regarding Claim 64, Lang modified by Johnson and Hajaj discloses the method of Claim 54. Lang further teaches of a method further comprising adjusting rotational alignment of the patient's joint (total knee replacement involving femoral and tibial component rotation, Claims 97-98 and 101-103).

Regarding Claim 65, Lang modified by Johnson and Hajaj discloses the method of Claim 54. Lang further teaches of a method further comprising adjusting linear alignment of the patient's joint (correcting axis of alignment during joint arthroplasty, Cl. 47, and correction may, for example, be designed to achieve a result wherein the femoral 3801 and tibial 3803 axes will coincide with the biomechanical axis 3805, Para. [0495]).

Regarding Claim 66, Lang modified by Johnson and Hajaj discloses the method of Claim 54. Lang further teaches of a method further comprising adjusting alignment of the patient's femur and tibia (joint alignment, Para. [0423], and total knee replacement involving femoral and tibial component rotation, Claims 97-98 and 101-103).

Regarding Claim 67, Lang modified by Johnson and Hajaj discloses the method of Claim 54. Lang further teaches of a method further comprising adjusting a biomechanical axis of the patient's joint (Paragraphs [0435], [0438] and [0439]).

Regarding Claim 68, Lang modified by Johnson and Hajaj discloses the method of Claim 54. Lang further teaches of a method further comprising adjusting an anatomical axis of the patient's joint (Paragraphs [0435], [0438] and [0439]).

Regarding Claim 69, Lang modified by Johnson and Hajaj discloses the method of Claim 54. Lang further teaches of a method further comprising balancing a patient's joint (Para. [0423] and Cl. 4).

Regarding Claim 70, Lang modified by Johnson and Hajaj discloses the method of Claim 69. Lang further teaches of a method further comprising assessing (determining joint space width of a knee joint using imaging scans, the medial and lateral joint space width may be compared and differences in medial and lateral joint space width can be utilized to optimize the desired postoperative correction in anatomical or biomechanical axis alignment based on this information, Para. [0228]) the balance of the patient's joint (ligament balancing, Para. [0423]).

Regarding Claim 71, Lang modified by Johnson and Hajaj discloses the method of Claim 69. Lang further teaches of a method further comprising adjusting the balance of the patient's joint (ligament balancing, Para. [0423], and subsequent adjustments and fine-tuning of surgical intervention, Para. [0496]).

Regarding Claim 72, Lang modified by Johnson and Hajaj discloses the method of Claim 69. Lang further teaches of a method wherein balancing of the patient's joint comprises balancing of the patient's joint in extension (ligament balancing, Para. [0423]).

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Continuation of:

Regarding Claim 73, Lang modified by Johnson and Hajaj discloses the method of Claim 69. Lang further teaches of a method wherein balancing of the patient's joint comprises balancing of the patient's joint in flexion (ligament balancing, Para. [0423]).

Regarding Claim 74, Lang modified by Johnson and Hajaj discloses the method of Claim 54. Lang further teaches of a method further comprising planning a surgical procedure based on electronic image data of the patient's knee (Parag. [0039]).

Regarding Claim 75, Lang modified by Johnson and Hajaj discloses the method of Claim 74. Lang further teaches of a method further performing the surgical procedure (performing image guided surgery, Para. [0437]).

Regarding Claim 76, Lang modified by Johnson and Hajaj discloses the method of Claim 74. Lang further teaches of a method further comprising planning the surgical procedure based on electronic image data of the patient's knee (Parag. [0039]) in order to achieve a predetermined surgical result (partial joint replacement or ligament repair, Para. [0437]).

Regarding Claim 77, Lang modified by Johnson and Hajaj discloses the method of Claim 76. Lang further teaches of a method wherein step b) substantially achieves the predetermined surgical result (partial knee joint replacement, [0437]).

Regarding Claim 78, Lang modified by Johnson and Hajaj discloses the method of Claim 76. Lang further teaches of a method wherein the surgical result includes joint balancing (Para. [0423]).

Regarding Claim 79, Lang modified by Johnson and Hajaj discloses the method of Claim 76. Lang further teaches of a method wherein the surgical result includes joint alignment (Para. [0423]).

Regarding Claim 80, Lang modified by Johnson and Hajaj discloses the method of Claim 54. Lang further teaches of a method further wherein step b) comprises inserting a first insert (insertion of tibial implant 2415, Fig. 26Y and Para. [0154]).

Regarding Claim 81, Lang modified by Johnson and Hajaj discloses the method of Claim 80. Lang further teaches of a method further comprising adjusting balance with a second insert (use of spacers in Parag. [0494], or trial implants in Paragraphs [0496]-[0497]).

Regarding Claim 82, Lang modified by Johnson and Hajaj discloses the method of Claim 80. Lang further teaches of a method further comprising adjusting alignment with a second insert (use of trial implant for intraopertative adjustment, Paragraphs [0496]-[0497]).

Regarding Claim 83, Lang modified by Johnson and Hajaj discloses the method of Claim 80. Lang further teaches of a method further comprising inserting a second insert (use of trial implant for intraopertative adjustment, Paragraphs [0496]-[0497]).

Regarding Claim 84, Lang modified by Johnson and Hajaj discloses the method of Claim 83, but fails to explicitly teach of a method further comprising replacing the second insert with a third insert. It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace a second insert with a third insert, such as replacing one trial implant with another trial implant, to improve ligament balance, since the use of trial implants to make adjustments before insertion of a permanent implant is well known in the art.

Regarding Claim 85, Lang modified by Johnson and Hajaj discloses the method of Claim 84, further teaches of a method further comprising adjusting balance with the third insert (balancing of knee using a number of spacers, Para. [0633]).

Regarding Claim 86, Lang modified by Johnson and Hajaj discloses the method of Claim 84. Lang further teaches of a method further comprising adjusting alignment with the third insert (joint alignment, Para. [0423]).

Claims 1-94 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.